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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,938	07/22/2002	Srinivas Kaveri	TJK/209	8718

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,938

Applicant(s)

KAVERI ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005 and 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-123, 141-143 and 151-154 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 86-109, 117-120 and 151-154 is/are allowed.
- 6) ☒ Claim(s) 110-116, 121-123 and 141-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Applicants have submitted an abstract in response to the last office action. However there is no amendment to the specification stating that this abstract is to be added. 37 CFR § 1.121(b)(1) states:

(1) Amendment to delete, replace, or add a paragraph. Amendments to the specification, including amendment to a section heading or the title of the invention which are considered for amendment purposes to be an amendment of a paragraph, must be made by submitting:

(i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a paragraph with one or more replacement paragraphs, or add one or more paragraphs.

Therefore the abstract must be submitted again with instructions in the amendment to add it to the specification at a particular point.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because at least the sequences on page 5, 7 and 20 are not labeled as to SEQ ID NO. Also, there is reference made to specific residues in the sequence of Factor VIII but the sequence of this protein is not included in the CRF or written sequences. Because the application could be examined without this disclosure this has been done but it must be included in the patent file before any patent can be issued.

Applicant states that "[t]he amino acid sequences of pp. 5, 7, 20, claims 111-113, 121-123, and 141-143...have been labeled as to their respective SEQ. ID Nos...[and that] [s]aid pages are filed herewith as hand-amended and clean versions". The sequences have been labeled in the instant claims but there is has been no amendment to pages 5, 7 or 20 received by the office as part of the amendments filed 8/1/05 or 8/21/05. Also, it is noted that "hand

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amended and clean versions" are not what is now required by 37 CFR § 1.121. According to the rule, the specification must be amended by deletion, replacement or addition of a paragraph; by replacement section or by substitute specification.

Applicants also state that "the Applicant hereby filed the written sequence of human Factor VIII". This has not been done. Also, as noted previously, not only the written sequence of Factor VIII must be filed but also the CRF.

The disclosure is objected to because of the following informalities:

The specification refers to figures but no figures were submitted with application filed on 1/22/02. Applicants state that "[f]igures 1-5, filed with the PCT application are hereby filed as an amendment", but this has not apparently not been done. There are no figures in the amendment filed 8/1/05 or 8/21/05.

There is no recitation of "Figure 3 A-D" in the Brief Description Of The Drawings. Neither is there an explanation of the different lanes or the conditions in A-D of the instant figure. [The examiner erroneously referred to Figures 3 A-C in the last action but applicants correctly deduced that 3 A-D were intended]. Applicants should be careful not to include "new matter" in adding this information. Applicants state that "Figures 3B and 3D refer to Patient 'Bor' and Figures 3A and 3C to Patient 'Wal'...[and that] [t]he rest is self-explanatory..." It is not pointed out where in the specification this explanation is found. Perhaps applicants can argue which figures refer to "Wal" and "Bor" by pointing out the rate of hydrolysis in each, as discussed on page 15, lines 23-29.

Appropriate correction is required.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 111-116, 121-123 and 141-143 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants state that "the isolated amino acid sequences in question are regions of cleavage of Factor VIII" and that these peptides are competitive inhibitors and "they thus 'prevent' or 'protect' the Factor VIII from being cleaved by the allo-antibody...[and that] [i]t is submitted that this is in fact deduction: the inventors have not demonstrated it". Thus it is presumed that applicants admit that a specific and substantial utility has not been asserted or is well established. Perhaps they can show that it is well established if they can show that these peptides are from Factor VIII and that one of ordinary skill in the art would recognize that they would be competitive inhibitors. However, the sequence of Factor VIII is not of record in the application, nor apparently is the site of cleavage by the allo-antibody (see statement regarding sequences *supra*). The addition of this sequence would probably not be new matter if applicants refer to where it is taught in the prior art.

Claims 114-116, 121-123 and 141-143 have been added to this rejection because applicants have not shown that the peptides or analogs of the peptides of the instant claims are useful as inhibitors and therefore it is maintained that they have no utility.

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Claims 111-116, 121-123 and 141-143 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 110 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 110 is indefinite in the recitation of "said sequencing". There is no antecedent basis for this phrase in claim 104. Applicants have changed "claim 104" to read "claim 1045", and there is no claim 1045. Applicants should have lined through or enclosed with double brackets the "4" in the instant claim or else they should have lined though "104" and added "105".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 111-113 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Ill, et al. (A), Lollar, et al. (B) or Voorberg (C). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that "the sequences of...[the instant references] are not isolated as are the heptapeptide sequences of the present invention, i.e. the heptapeptides of the present invention are isolated discrete molecules the N-terminus of which is a primary NH₂ group, and the C-terminus of which is a -COOH group, unlike the non-isolated protein sequences of...[the instant references] wherein the groups are present as an amide, -NHCO-, group in a chain" (emphasis in original). It is maintained that the sequences of the instant references are isolated as the term is normally understood, i.e. that it has been separated from at least some of the other substances in cells. There is no requirement in the instant claims that the sequence "have a primary NH₂ group, and...a -COOH group". Adding "consisting of" language to the instant claims would overcome this rejection.

Claims 86-109, 117-120 and 151-154 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-

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0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
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Patterson
November 10, 2005